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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,472	10/11/2001	John E. Sims	2932-B	9942

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EXAMINER
ANDRES, JANET L

ART UNIT	PAPER NUMBER
1646	11

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,472	SIMS ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 29 May 2003 is acknowledged. Claims 1-10 are pending and under examination in this application.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.

3. The rejection of claims 1, 4, 7, and 10 under 35 U.S.C. 102(a), 102(b), and 102(e) as anticipated by WO 01/42091, US patent 5,945,310, and US application 2002/0068279 is withdrawn in response to Applicant's amendment.

4. The rejection of claims 1, 4, 7, and 10 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

Claim Rejections/Objections Maintained

5. The denial of priority is maintained for reasons of record in the office action of paper no. 11 and further discussed below. Since no utility is disclosed in the provisional application, the priority date is the filing date of the instant application, 11 October 2001.

6. The rejection of claims 1-10 under 35 U.S.C. 101 is maintained for reasons of record in the office action of paper no. 11.

a. Applicant argues that not every polynucleotide would map to the 2q11-12 region of the chromosome. Applicant argues that by the same standard of specificity antibodies do not have specific utilities because all antibodies bind to some antigen somewhere.

Applicant's arguments have been fully considered but have not been found to be persuasive. An antibody that was only known to bind to some antigen somewhere would not have a specific and substantial utility. An antibody that was known to bind to some protein in particular might, if

there was a utility associated with the ability to identify that particular protein, regardless of how many other antibodies bound to the same protein. Similarly, if the application disclosed a utility associated with the mapping of the instant polynucleotide to 2q11-12, that polynucleotide would have a utility. However, no such utility is disclosed by the instant specification. All that is taught is on p. 27 is that chromosome 2 is associated with various abnormalities. There is no suggestion as to how the instant polynucleotide could be used to identify these abnormalities. In the current amendment, Applicant provides six examples of conditions that were found to be associated with the proximal region of chromosome 2 and argues that the polynucleotide, since it is also located on the proximal region of chromosome 2, would be useful to identify these conditions. However, there is nothing in the specification that contemplates such specific uses: all that is presented is a list of conditions found on the chromosome for which the polynucleotide might be a useful marker. *See In re Kirk*, 153 USPQ 48, 53 (CCPA 1967) quoting the Board of Patent Appeals,

'We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates.'

b. Applicant argues that the encoded polypeptides can be used for protein purification, for purification of cells that bind to it, as carriers, and as research tools. Applicant additionally states that the polypeptides can be used to develop antibodies that distinguish between IL-1 family members.

This is not found to be persuasive because, as stated in the office action of paper no. 11, there is no specific and substantial utility associated the polypeptide. There is no "real world" use associated with the study of cells that bind to protein whose significance itself is unknown. Applicant has further not identified any such cells; thus, clearly further research would be required before the polypeptides could be used as targeting agents. The use of a protein whose function is unknown to make antibodies is a research use with the intended goal of discovering characteristics or functions of the protein, not a use for the protein itself.

c. Applicant further argues that a new member of the Il-1 family could be used to study the IL-1 family. Applicant states that IL-18, a member of this family, is involved in inflammation. Applicant further argues that both upregulating and downregulating are critical to the inflammatory response. Applicant concludes that the specification asserts numerous "real world" utilities.

Applicant's arguments have been fully considered but have not been found to be persuasive. To use a new protein whose function is not known to "study" the IL-1 family would require a study of the function of the protein itself. As stated above, the use of a protein to study itself is not a substantial, real-world utility. There is no "specific benefit in currently available form" associated with comparison of a protein of unknown function with other family members; the purpose of such a study would be to discover the function of the protein itself.

It was not stated in the previous office action that IL-18 is not involved in inflammation. What was stated was that the members of the IL-1 family, including IL-18, had different effects. That a protein is involved in inflammation does not teach how to use that protein. Clearly, proteins that upregulate a process have different uses than proteins that downregulate a process,

and knowledge of what effect a particular protein would have would be necessary in order to use it. The mere knowledge that a protein might be involved in a process does not provide it with a utility. As Applicant states, clarifying the role of the various family members is a necessary step in developing therapeutic agents. Merely identifying an protein as a member of this family is not sufficient. Since the role of IL-1eta in inflammation has not been clarified, it lacks a "real world" utility.

7. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, as lacking enablement because the claimed invention lacks utility is maintained for the reasons set forth above and in the office action of paper no. 11.

8. The rejection of claims 1, 4, 7, and 10 under 35 U.S.C. 112, first paragraph, as lacking enablement are maintained for reasons of record in the office action of paper no. 11.

Applicant has amended the claims to recite nucleic acid molecules of 98% identity. Applicant argues that claims 1 and 2 do not require that the encoded polypeptide bind a receptor and thus that the arguments for non-enablement are not relevant.

Applicant's arguments have been fully considered but have not been found to be persuasive. It is noted that claim 2 was not included in this rejection because, while it encompasses molecules with different structures, the entire coding region of the polynucleotide is included. Claims 1, 4, 7, and 10, however, encompassed and still encompass variants that would not predictably have the same characteristics as the disclosed sequence. Since there is no functional description, it is unpredictable as to which variants, if any, would have the same function. Even a single amino acid change can alter the characteristics of an encoded protein; absent a known function and a functional limitation in the claims, the skilled artisan could not

predictably make and use polynucleotides that encoded or identified proteins with the same characteristics. That the claims provide no functional limitations does not serve to enable them, but rather the reverse: without a functional limitation, or other identifying characteristics, the skilled artisan could not make and use similar molecules because there is no way to identify molecules with similar characteristics.

9. The rejection of claims 1, 4, 7, and 10 under 35 U.S.C. 112, first paragraph, as lacking sufficient written description is maintained for reasons of record in the office action of paper no. 11.

Applicant's amendment is not sufficient to overcome this rejection. There is no function known for the encoded protein, and no functional limitation in the claims. Since Applicant has taught no structural characteristics or other features by which one of skill in the art could identify an IL-1eta polynucleotide, the artisan would not be able to identify other molecules having the characteristics of the disclosed polynucleotides and would not conclude that Applicant was in possession of the genus of IL-1eta polynucletoides having 98% homology to the disclosed sequence.

10. The rejection of claims 1-10 under 35 U.S.C. 102(b) as anticipated by Smith et al. is maintained for reasons of record in the office action of paper no. 11.

Applicant argues that, since the provisional application teaches a utility, Applicant is entitled to priority to that application. However, since, for reasons of record in the office action of paper no. 11 and above, the claimed invention lacks utility, Applicant is not entitled to priority to the provisional application.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that

sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
July 31, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER